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10/030,549	01/11/2002	Willy Deleersnijder	01975.0032	8772

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EXAMINER

GUCKER, STEPHEN

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 05/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/030,549

Applicant(s)

Deleersnijder

Examiner

Stephen Buckner

Group/Art Unit

1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 12/5/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-25 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 1-25 are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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*Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9, 11-12, 23 (in part) and 25, drawn to nucleic acid, vectors, host cells, and method of making protein, classified in class 536, subclass 23.5, for example.
  - II. Claims 10, 13-14, and 23 (in part), drawn to protein or membrane preparation, classified in class 530, subclass 350, for example.
  - III. Claim 15, drawn to antibody, classified in class 530, subclass 387, for example.
  - IV. Claims 16(a), drawn to a method of agonist treatment, classification dependent on the chemical nature of the agonist, potentially classified in class 424+ or 514+ for example.
  - V. Claim 16(b) and 17(b), drawn to gene therapy, classified in class 514, subclass 44, for example.
  - VI. Claims 17(a), drawn to a method of antagonist treatment, classification dependent on the chemical nature of the agonist, potentially classified in class 424+ or 514+ for example.
  - VII. Claims 17(c), drawn to a method of treatment with a solubilized receptor, classified in class 514, class 300-350, for example.
  - VIII. Claim 18, drawn to diagnostic genetic analysis of polynucleotides and gene expression, classified in 435, subclass 6+, for example.

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- IX. Claims 19 and 21, drawn to screening assays, classified in 435, subclass 7.1 or 7.2+, for example.
- X. Claim 20, drawn to an agonist, classification dependent on the chemical nature of the agonist, potentially classified in class 424+ or 514+ for example.
- XI. Claim 22, drawn to an antagonist, classification dependent on the chemical nature of the agonist, potentially classified in class 424+ or 514+ for example.
- XII. Claim 24, drawn to making a nonhuman transgenic animal, classified in class 800, subclass 21, for example.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for "inventive groups that are directed to different products; restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons:

Groups I-III and X-XI are directed to products that are distinct both physically and functionally, and are therefore patentably distinct, each group from the other, and are not required one for the other. Further, the nucleic acid of Group I can be used other than to make the protein of Group II, such as its use in hybridization probes. The antibody of Group III can be used other than to detect the protein of Group II, such as its use in isolating and purifying the protein from its natural source by affinity chromatography. The protein of Group II can be used other than to make the antibody of Group III, such as its use diagnostically or therapeutically. The agonist of

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Group X and the antagonist of Group XI have different structures and function in diametrically opposed ways in relation to the protein of Group II.

Group I and any of Groups V, VIII, or XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid of Group I can be used to make the protein of Group II.

Group II and any of Groups VII or IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the protein of Group II can be used to make the antibody of Group III.

Group X and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the agonist of Group X can be used to detect or purify through affinity chromatography the protein of Group II.

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Group XI and Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antagonist of Group XI can be used to detect or purify through affinity chromatography the protein of Group II.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for "inventive groups that are directed to different methods; restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

Groups IV-IX and XII are directed to methods that comprise different process steps that are distinct both physically and functionally, and are therefore patentably distinct, each group from the other, and are not required one for the other. The various methods are performed for different and distinct purposes and lead to different and distinct outcomes or results. Further, the agonist used in Group IV is not used in or produced by the methods of Groups V-IX and XII. The antagonist of Group VI is not used in or produced by the methods of Groups IV-V, VII-IX, and XII. The vector used in Group V is not used in or produced by the methods of Groups IV and VI-IX and is materially different from the vector used in Group XII. The solubilized receptor of Group VII is not used in or produced by the methods of Groups IV-VI, VII-IX, and XII. The nucleic acids used in Group VIII are not used in or produced by the methods of Groups IV, VI-

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VII, and IX and are materially different from the vectors used in Groups V and XII. The screening assays of Group IX do not use or produce the vectors used in Group XII.

The product of Group III is not used in or produced by the methods of Group IV-IX and XII, and are distinct, one from the other.

The product of Group I is not used in or produced by the methods of Group IV, VI-VII, and IX, and are distinct, one from the other.

The product of Group II is not used in or produced by the methods of Group IV-VI, VIII, and XII, and are distinct, one from the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate classifications and because the literature searches required for the inventions are not co-extensive and therefore references that would anticipate one invention would not necessarily anticipate or even make obvious the other invention, restriction for examination purposes as indicated is proper. Furthermore, there are different issues for the search and examination of each, which would also be unduly burdensome.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

May 12, 2003

*Gary L. Kunz*  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
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